

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

***Status of the Claims***

In the present Amendment, claims 10-30 and 32-37 have been amended, and claims 1-9, 38-50 have been canceled without prejudice or disclaimer of the subject matter contained therein. Thus, claims 10-37 are pending in the present application.

No new matter has been added by way of these amendments. Claims 10-24 have been amended into independent form. For the amendment to claim 25, Applicants note Example 5, preparation method 1 (page 37, line 8); for claim 26, see Example 5, preparation method 2 (page 37, line 25); for claim 27, see Example 6 (page 38l; line 8); for claim 28, see Example 7, preparation method 1 (page 38, lines 18-19); for claim 29, see Example 7, preparation method 2 (page 37, line 23); for claim 30, see Example 7, preparation method 4 (page 39, line 21); for claim 32, see Example 9 (page 41, line 15); ); for claim 33, see Example 10 (page 41, last line); for claim 34, see Example 11, preparation method 1 (page 42, line 20); for claim 35, see Example 12, preparation method 1 (page 43, line 12); for claim 36, see Example 12, preparation method 2 (page 43, line 24); and for claim 37, see at least at page 30, lines 22-23. The amendment to claim 49 actually deletes subject matter.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

***Issues under 35 U.S.C. § 112, First Paragraph (Enablement)***

Claims 1-3 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement by reciting solvates (see pages 2-4 of the Office Action).

Also, claim 5 stands rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement by reciting hydrates (see pages 4-5 of the Office Action).

Further, claims 38 and 48 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement by reciting the prevention of diseases (see pages 6-7 of the Office Action).

Claims 1-3, 5, 38 and 48 have been canceled, thereby rendering these rejections moot. Thus, withdrawal of these rejections is respectfully requested.

***Issues under 35 U.S.C. § 112, First Paragraph (Written Description and Enablement)***

Claims 38-49 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of written description (see page 8 of the Office Action) and lack of enablement (see pages 8-13 of the Office Action). Overall, the Examiner questions the nexus between the modulation of the c-Kit kinase receptor and a useful treatment of a disease/condition. The disputed claims have been canceled rendering the rejections of these claims moot. Thus, withdrawal of these rejections is respectfully requested.

***Issues under 35 U.S.C. § 112, Second Paragraph***

Claims 38-48 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see page 13 of the Office Action). The disputed claims have been canceled, thereby rendering this rejection moot. Withdrawal of this rejection is respectfully requested.

***Issues under 35 U.S.C. § 101***

Claim 50 stands rejected under 35 U.S.C. § 101 as being directed to a “use” without reciting any process steps (see page 13 of the Office Action). This claim has been canceled, thereby rendering this rejection moot. Withdrawal of this rejection is respectfully requested.

***Issues under 35 U.S.C. § 102(e)***

Claims 1-9 and 25-49 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Funahashi *et al.* ‘286 (U.S. Patent No. 7,253,286) (see page 14 of the Office Action). Some of the disputed claims have been canceled, rendering the rejection of these claims moot. With respect to the remaining claims, Applicants respectfully traverse.

In the Office Action (paragraph 10), the Examiner refers to Examples 395 and 396 at columns 280-281 of Funahashi *et al.* ‘286. Applicants note that Example 368 corresponds to the compounds of the present invention, and this compound is even discussed in paragraph [0002] (page 1) of the present specification. In this regard, the cited Funahashi *et al.* ‘286 reference fails to disclose a salt of the compound of Example 368. The compound of Example 368 was not obtained as a salt, while the salt of the compound of the present invention is methanesulfonate or ethanesulfonate. Funahashi *et al.* ‘286 fails to disclose all claimed features.

Furthermore, Applicants note the powder X-ray diffraction pattern of Reference Example 1 as shown in Figure 2 of the present specification. Reference Example 1 in the specification of the present application corresponds to Example 368 of Funahashi *et al.* '286. In contrast, Figures 7-13 show the powder X-ray diffraction patterns of Forms A, B, C, F, I  $\alpha$  and  $\beta$  of the present invention. It is clear that the powder X-ray diffraction patterns of the present invention versus that of Reference Example 1 (or Funahashi *et al.* '286) are different.

Thus, this rejection has been overcome. The Federal Circuit reiterated what the test for anticipation involves: "The single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention." See *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research*, 64 USPQ2d 1292, 1296 (Fed. Cir. 2002) (citing *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). That is not the case here, as the Funahashi *et al.* '286 reference does not disclose all instantly claimed features.

Based on the above, reconsideration and withdrawal of this rejection are respectfully requested.

***Issues of Obviousness-Type Double Patenting***

Claims 1-49 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over the claims of copending Application No. 10/553,927 or copending Application No. 11/472,372.

Applicants respectfully traverse because the claimed salt forms do not overlap in scope with that of the amorphous forms of the cited '372 application. Applicants also note that the claims of the '372 application have been amended to recite "having no noticeable peak in a powder X-ray diffraction" which clearly distinguishes from the salts of the present invention.

Further, Applicants note that the cited '927 application has been abandoned, and thus there would be no double patenting.

Thus, patentable distinctions exist for the present invention. Reconsideration and withdrawal of these rejections are respectfully requested.

***Conclusion***

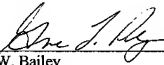
A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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